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Please find below and/or attached an Office communication concerning this application or proceeding.

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SUPPLEMENTAL EXAMINER'S ANSWER RESPONDING TO A REMAND

FOR FURTHER CONSIDERATION OF REJECTION

1. Pursuant to the remand under 37 CFR 41.50(a)(1) by the Board of Patent Appeals and Interferences on 21 June 2007 **for further consideration of a rejection**, a supplemental Examiner's Answer under 37 CFR 41.50(a)(2) is set forth below:

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/712,615
Filing Date: November 13, 2000
Appellant(s): BUECHLER ET AL.

Barry Wilson
Reg. No. 39,431
For Appellant

SUPPLEMENTAL EXAMINER'S ANSWER

This is in response to the appeal brief filed 17 November 2005 appealing from the Final Office action mailed 5 May 2005.

(1) Real Party in Interest

A statement identifying Biosite Incorporated (formerly Biosite Diagnostics, Inc.) by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

This appeal involves claims 27, 28, and 93-128.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

A.	5,458,852	BUECHLER	October 17, 1995
B.	5,242,837	SLOVACEK et al.	September 7, 1993
C.	4,444,879	FOSTER et al.	April 24, 1984

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

I. Claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Buechler (U.S. Patent #5,458,852).

Buechler discloses assay devices meeting the requirements of the instant invention. This is supported by the specification on page 59, lines 21-28. Particularly Buechler's device comprises a reaction chamber (column 6) and a diagnostic lane (column 10 –diagnostic element). See figures 1-5, item #4 (reaction chamber, column 6 and 7), item #17 (optional reagent chambers, column 8 and 9, and item # 6 (diagnostic element, column 10).

The device includes a time gate for measuring the reaction in a given period of time. Please see column 7 lines 41-45. The device is useful in measuring an absolute signal or a rate of change of the signal.

Particularly determining the presence or amount of each target ligand in the sample either visually or instrumentally, column 17, lines 44-46. The rate of change is monitored via the flow rate of reagents through the porous member, column 18, lines 2-9. Further the label (signal development element) does not appreciably bind to any reagent in said assay device but could be designed to indirectly cause a visually or instrumentally detectable signal because of the assay process, column 3, lines 17-25.

The apparatus of Buechler further includes an optical system for detecting and processing optical signals generated from the label in the diagnostic lane. Column 20 lines 22-31.

As illustrated in Figure 1, Buechler discloses "diagnostic testing devices for determining the presence or amount of at least one target ligand' which comprise "various elements, [including] a sample addition zone **1**, a sample addition reservoir **2**, a sample reaction barrier **3**, a reaction chamber **4**, a time gate **5**, a diagnostic element **6**, and a used reagent reservoir **7**" (Buechler, Fig.1 and col. 4, 1. 63, to col. 5, 1, 3). The diagnostic element contains one or more capture zones, and "various means can be used for the detection of signal at the capture zone of the diagnostic element....[including] visual and instrumental means, such as spectrophotomeric and reflectance [means]" (id. At col. 11, II. 21-31).

Focusing on Buechler's "time gate,", Buechler teaches that "the time gate **5** holds the reaction mixture in the reaction chamber **4** for a given period of time.., relative to the assay process such that the reactions which occurs in the reaction chamber **4** as a result of the assay process will reflect the presence or amount of target ligand in the sample. Thus, the time gate **5** delays the flow of the reaction mixture onto the diagnostic element **6**" (Buechler, Fig. 1A, col. 7, 11.41-53).

Buechler, in discussing the diagnostic element, and referring to Figures 1 and 2, teaches that "capture zones are comprised of reagents, such as receptors....which bind or react with one or more components from the reaction mixture. The binding of the reagents from the reaction mixture to the capture zones of the diagnostic element 6 is related to the presence or amount of target ligand in the sample" (Buechler, col. 10, 11. 10-19). These "capture zones" appear to be the same as the claimed "assay zones" because they are configured to bind analyte, the same function the "assay zones" are required to have by the claim. Moreover, Buechler's receptors "can be placed in discrete zones" (*id* at col. 10, 11. 21-23). In addition to the reagents that bind or react with the target ligand, Buechler teaches that "[r]eceptors or other chemical reagents, for example, a receptor against the signal generator can also be immobilized on the diagnostic element **6** to verify to the user that the reagents of the reaction mixture are viable and that the reaction mixture passed through the zones of the receptors or biosensors" (*id.* at col. 10, 11. 24-29).

Buechler describes a positive control analogous to the independent assay control described in the present specification. See Buechler, col. 14, II. 25-66. *"The reaction mixture may also flow over a positive control zone, which can be for example, an immobilized receptor to the signal development element:....."* Buechler's positive control appears to be designed to independently confirm that the assay reagents have actually passed over the capture zones, i.e., that the assay has run to completion.

Since the signal-producing reagent used to detect the target in the capture zone(s) is the same signal-producing reagent that binds to the positive control, it is logical to assume that the capture zone(s) and the positive control zone are separate, discrete zones on the surface of the diagnostic element. Otherwise, the target and control signals would be indistinguishable. Moreover, it is logical to assume that Buechler's device is configured such that both the positive control zone and the capture zone can be accessed visually or instrumentally to determine whether the signal producing reagent has contact both zones. Consequently, the claimed optical component appears to be anticipated by the cited reference of Buechler.

In the alternative, Buechler differs from the instant invention in not specifically disclosing the detailed structure of the optical system including an optical component and a signal processor specifically configured to read electronic signals. In particular, while Buechler's "time gate" is in fluid communication with a reaction chamber and an assay zone, and in use, contains optically detectable labels, Buechler's optical component is not appropriately configured (Br.17) to detect a signal from the optically detectable label within the time gate.

However, even if the claimed assay device is not identical to the device of Buechler with regard to the configuration of the optical component to allow for detection in the "time gate", the differences is deemed obvious because one of ordinary skill in the art would have been motivated to measure the label reagents in the "time gate" in order to detect the reagents through out the device as a means of tracking reagent flow, assay progression, and assay completion.

In other words, Buechler's device contains a positive control analogous to the independent control described in the present specification. The positive control appears to be designed to independently confirm that the assay reagents have actually passed over the capture zones, i.e., that the assay has run to completion. It would have been prima facie obvious to include an optical system in the device of Buechler such that the positive control and the capture zone can be accessed visually or instrumentally in order to determine the signal producing reagents within the device. This would allow for the detection of all the labeled reagents and their effects within the assay device. Absent evidence to the contrary the invention is alternatively considered obvious.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

II. Claims 95 and 117 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler (U.S. Patent #5,458,852) in view of Slovacek et al. (U.S. Patent#5,242,837).

Please see Buechler (U.S. patent #5,458,852) as set forth above.

The primary references do not particularly exemplify the use of a fluorometer as a useful optical detector.

However, fluorometers are routinely utilized to detect specific binding reagents. This point is supported in the patent of Slovacek et al. Therefor the use of a fluorometer is routine optimizations that are almost always determined and used in immunoassay studies.

Unless the result obtained in the instant application is a significant and unexpected difference over the prior art, it would have been prima facie obvious for one of ordinary skill in the art to employ different known detectors in the given parameters to determine the unknown as a means of optimizing the device provided by the art.

III. Claims 28, 101, 102, 104, 107-108 and 127-128 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler (U.S. Patent #5,458,852) in view of Foster et al. (U.S.Patent#4,444,879).

The teachings of Buechler (U.S. patent #5,458,852) as set forth above. However, these references fail to teach the assay as a kit.

However, kits are well known embodiments for assay reagents. Foster et al. (U.S. Patent #4,444,879) describe one example. In their patent kits including the reactant reagents, a micro plate, positive controls, negative controls, standards, and instructions are taught. See figure 6, and column 15, lines 10-34.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the detection assay as taught by Buechler (U.S. patent #5,458,852) and format them into a kit because Foster et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay.

IV. Claim 103 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler (U.S. Patent #5,458,852) in view of Foster et al. (U.S.Patent#4,444,879) as applied to claims 28, 101, 102, 104, 107-108 and 127-128 above, and further in view of Slovacek et al. (U.S. Patent#5,242,837).

Please see Buechler (U.S. patent #5,458,852) in view of Foster et al. as set forth above.

The primary references do not particularly exemplify the use of a fluorometer as a useful optical detector.

However, fluorometers are routinely utilized to detect specific binding reagents. This point is supported in the patent of Slovacek et al. Therefor the use of a fluorometer is routine optimizations that are almost always determined and used in immunoassay studies.

Unless the result obtained in the instant application is a significant and unexpected difference over the prior art, it would have been prima facie obvious for one of ordinary skill in the art to employ different known detectors in the given parameters to determine the unknown as a means of optimizing the device provided by the art.

Allowable Subject Matter

2. Claims 97, 98, 105, 106, 119, and 120 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered.

4. The information disclosure statements filed 25 July 2007 has been considered as to the merits.

5. The appellant must within **TWO MONTHS** from the date of the supplemental examiner's answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the rejection for which the Board has remanded the proceeding:

(1) **Reopen prosecution.** Request that prosecution be reopened before the examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit, or other evidence. Any amendment, affidavit, or other evidence must be relevant to the issues set forth in the remand or raised in the supplemental examiner's answer. Any request that prosecution be reopened will be treated as a request to withdraw the appeal. See 37 CFR 41.50(a)(2)(i).

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. If such a reply brief is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened under 37 CFR 41.50(a)(2)(i). See 37 CFR 41.50(a)(2)(ii).

6. Extensions of time under 37 CFR 1.136(a) are not applicable to the **TWO MONTH** time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

7. A Technology Center Director or designee has approved this supplemental examiner's answer by signing below:

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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